VALUE IN HEALTH REGIONAL ISSUES 1 (2012) 223–227

Available online at www.sciencedirect.com
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journal homepage: www.elsevier.com/locate/vhri

Status Update of the Reimbursement Review Environment in the Public Sector across Four Latin American Countries

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ABSTRACT

In Latin America, social security and public sectors represent the largest financiers and providers of health care. Many countries in the region have compulsory packages of basic health care benefits. As part of an effort to improve quality of care and access, several health technology assessment agencies, both governmental and academia, among a number of Latin American countries have been formally established in the past few years. Several Latin American countries have recently developed and published methodological guidelines in economic evaluation, indicating that there is a growing interest in evaluating health-related products, drugs, and technologies used by the population. Presentations on the health care system and the role of health technology assessment, pharmacoeconomics, and risk sharing policies, from the public sector perspective, in the Latin American countries Argentina, Brazil, Colombia, and Mexico were made at the 3rd Latin American ISPOR Conference held in Mexico City in 2011 and are discussed in this article. In conclusion, there is a clear need for Latin American countries to evaluate the value of new technologies that are being incorporated into their health care system. In addition, health technology assessment guidelines are important for their local needs in terms of regulation along with common country unions. In the future, the Latin American region needs to increase drug access along with implementing cost-containment measures to improve quality and health outcomes.

Keywords: health technology assessment, Latin America.

Introduction

The health care system in Latin America is highly fragmented and has subsystems that target specific strata of the population grouped by social class, income, occupation, type of employment, ethnic origin, or urban or rural residence, producing a phenomenon of population segregation that has led to higher segmentation, fragmentation, and low efficiency [1].

To address the fragmentation of the health care systems in the region, the Organizacion Panamericana del Salud (Pan-American Health Organization) created a new health technology assessment (HTA) network in the Americas (Red de Evaluación de Tecnologías Sanitarias), which triggered the HTA development in Latin America [1,2]. As part of this initiative, countries representing Mercosur (Brazil, Argentina, Paraguay, and Uruguay) and Grupo Andino (Bolivia, Chile, Colombia, Ecuador, Peru, and Venezuela) commenced focusing their efforts on the implementation of HTA. Currently, Mercosur has guidelines for HTA methods, new technologies, and economic evaluation. The Grupo Andino is also working toward developing methodological HTA guidelines [1,2].

There are several HTA agencies, both governmental and academia, among a number of Latin American countries, which were formally established in the last couple of years. Countries such as Cuba, Brazil, and Mexico have recently developed and published methodological guidelines in economic evaluation, indicating that there is a growing interest in evaluating health-related products, drugs, and technologies used by the population [3,4].

In 2009, during the 2nd ISPOR Latin America Conference held in Rio de Janeiro, Brazil, the first symposia was held to discuss questions on HTAs, decision-making reimbursement, and pharmacoeconomics to support each country's needs at that time, with a focus on four Latin American countries (Argentina, Brazil, Colombia, and Mexico) [5]. To provide an update on the information presented in 2009, at the 3rd Latin America Conference held in 2011 in Mexico City, Mexico, a second symposia served to discuss the health care reimbursement environment and

Conflicts of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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http://dx.doi.org/10.1016/j.vhri.2012.09.007

risk-sharing agreements for the same four Latin American countries (Argentina, Brazil, Colombia, and Mexico).

In Latin America, social security and public sectors represent the largest financiers and providers of health care. Many countries in Latin America have compulsory packages of basic health care benefits. What follows are country-specific updates of the public sector environment in Argentina, Brazil, Colombia, and Mexico concerned with the reimbursement environment and HTA based on the presentations and discussions at the 2011 3rd Latin American ISPOR Conference held in Mexico City [6].

Mexico

The Mexican health care system is divided into public (social security and Ministry of Health) and private (employers and self-pay), with only 64.6% of its population having health insurance [7]. The Mexican general law of health assigns to the Ministry of Health the responsibility to elaborate Mexican official norms of the sector and gather sanitary statistics. Under the Ministry of Health, Mexico has a general health council, which is the body of the Mexican state and is the health authority across the country. The Mexican council is assigned the responsibility to elaborate, review, and maintain permanent updates of the data of formulary drugs and studies and serves to resolve requests for updating the formulary drugs of the providers of health, scientific organizations, and suppliers [7].

According to the general law of health, before each new technology is introduced to the national market for its consumption, it must first obtain a sanitary registry. This request is made to the "Comisión Federal para la Protección contra Riesgos Sanitarios" [8], a commission that evaluates safety and efficacy of the product at issue.

Since 2000, once a product is in the national market it needs to be included in the formulary called "Basic Formulary Medications" and medicine catalogue made available through the Public System of Social Security. The private system of national health has the freedom to use drugs that are not included among the Basic Formulary Medications.

In 2007, to better evaluate health products and technologies available to the Mexican population, a program of action specific to HTA was established. HTA reports and recommendations are provided by university research centers and medical societies to the general health council and the minister of health to inform the Ministry of Health, payers, and providers. Since 2003, pharmacoeconomic studies are regarded as being mandatory as part of the HTA submission. To ensure the quality of the economic evaluations generated for the Council of General Salubrity, the academy and the pharmaceutical industry published in 2008 the "Guide for the conduction of studies of economic evaluation for the update of the Basic Formulary Medications of consumptions of the health sector in Mexico" [9].

As of 2003, in Mexico, there has been a growth in the development of economic evaluations with the intended purpose to fulfill the requirements for inclusion to the Basic Formulary Medications. These economic evaluations are, for the most part, presented to providers who have requested an update of the Basic Formulary Medications. Apart from those created by the government, some of the economic evaluations are also performed by academic groups and private consultants.

To perform HTAs in Mexico, the Center of National Health Technology (Centro Nacional de Excelencia Tecnológica en Salud) was instituted, which is a Ministry of Health agency. Its main purpose is to produce objective, reliable, and timely information related to health technologies. It is organized into three main programs: 1) medical equipment planning, to provide information on medical equipment as well as to supply the National Health Care System with information on the incorporation of medical devices; 2) the HTA, generating evidence to aid decision making from the Ministry of Health and the general health council; and 3) e-Health, to generate health information to the national health care system and communication of technologies [10].

Brazil

The Brazilian Constitution (1988) states that the country is responsible for providing heath care access to every Brazilian citizen [11]. For this reason, the Brazilian health care system is composed of a public mandatory, tax-based unified system (Sistema Único de Saúde) as well as an optional, premium-based private health care system, frequently provided through employers representing 75% of the private care system. The Brazilian health care system is organized into three categories: 1) the Ministry of Health (major policies), representing the entire country; 2) state secretaries of health, representing on a state level; and 3) municipal secretaries of health, on the city level (general practice, primary care services) [12].

The Ministry of Health is responsible for the development of a formulary, listing the drugs to be available to the entire Brazilian population at no cost to the patient in what is called RENAME (essential drug list). RENAME contains drugs that are approved by Agência Nacional de Vigilância sanitária (ANVISA), have proven effectiveness, and are indicated for diseases that affect a large population. In the past decade, another list was created to cover exceptional drugs or high-cost drugs that, after evaluation by the Ministry of Health, are considered effective and needed, and must be available at no cost for the entire Brazilian population [13].

There are two regulatory agencies, the National Agency for Private Health Care (ANS) and the National Health Surveillance Agency (ANVISA) [14,15]. ANS is an agency that oversees the relationship between patients and insurance companies to ensure transparency [15]. ANVISA is responsible for licensing, registering, and pricing of drugs, devices, equipments, and medical products in the country. It is illegal for patients in Brazil to consume drugs or utilize procedures that are not regulated and approved by ANVISA [16]. Until 2003, ANVISA would make decisions based exclusively on safety and effectiveness; however, in 2003, a governmental council that aims to economically regulate the market of drugs in Brazil (Chamber of Medicine) was created to evaluate the price of new health products as well as establish a cap to the annual price increase for drugs [17].

In December 2006, the Ministry of Health approved a national policy to evaluate and manage health care technologies requiring a description of technology, identification of submitter, number of ANVISA registry, proposed price approved by ANVISA, technical report presenting the scientific evidence of safety, efficacy/effectiveness comparing the proposed technology with the available and current technology, economic evaluation (cost-effectiveness and cost-utility evaluation) when there is a trade-off involving effectiveness, costs, and a budget impact analysis; however, it is market driven.

In 2011, the Brazilian Congress approved a new bill establishing the following [16]:

1. The establishment of the National Council for the Incorporation of Medicines and Products for Health (Comissão Nacional de Incorporação de Tecnologias [CONITEC]) in substitution of the Commission for Incorporation of Technologies. CONITEC includes representatives of Ministry of Health secretaries, ANVISA, ANS, National Council of Health Secretaries, National Council of Municipal Health Secretaries, and Federal Council of Medicine.
2. Decisions for listing products should be completed within 180 + 90 days after the submission of the dossier.

Once approved for listing, the product should be readily available in the health care system within 180 days.
3. Dossiers can be submitted to CONITEC throughout the year.
4. Medicines and products for health should be used according to the clinical guidelines approved by the Ministry of Health.
5. It is illegal to list, pay for, or reimburse any drug or procedure not registered by ANVISA.

Currently, risk-sharing negotiations/proposals are not part of the approval and decision-making process and have rarely been discussed at Brazilian scientific meetings, pharmaceutical companies, or academia. According to the current Brazilian regulation, risk-sharing negotiations are not allowed but discussions regarding these programs have started and the scenario may potentially change in the next few years. Brazil has a two-step decision process when defining costs. The first step is performed by ANVISA and considers safety, efficacy, and price. At this point, ANVISA will use international reference pricing. The second step commences once the drug is approved by ANVISA and is ready to be commercialized in Brazil, whereby the Ministry of Health, through the CONITEC, utilizes HTA data to define whether a drug should be included in the formulary and therefore available at no cost to all appropriate patients. There is no official threshold to guide decision making with regard to cost-effectiveness and the decision of including a drug on the formulary [15–17].

Argentina

Argentina is a federal country with 40 million people and 24 provinces. For this reason, the Argentine health care system is highly fragmented, whereby each of the 24 provinces has its own health care system. Social security (obras sociales), provided by 300 organizations, covers 47% of the health care expenses, followed by the public sector (35%), private sector (10%), and Instituto Nacional de Servicios Sociales para Jubilados y Pensionados, which is insurance to the elderly, which serves 8% of the population. Currently, the Ministry of Health and social security are the biggest consumers of health information [18].

HTA activities are thus decentralized, without a national HTA agency or health economic guidelines. In 2009, a governmental unit was created to coordinate HTA efforts within national bodies: the de Evaluación y Ejecución de Tecnologías en Salud or The National Coordination Unit of Health Technology Assessment and Implementation. The de Evaluación y Ejecución de Tecnologías en Salud is formed by representatives of 12 areas of the Ministry of Health, ranging from the national regulatory agency (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica), the Superintendence of Social Services that regulates social security, national hospitals, to Instituto Nacional de Servicios Sociales para Jubilados y Pensionados (the elderly insurance). Its main objectives are to coordinate the different bodies to ensure access to HTA information to health authorities and citizens [19].

The Superintendence of Health is the body that regulates the social security sector and has a compulsory package of services (Programa Médico Obligatorio) whose creation was informed by HTA principles. A recent law was passed in 2011 to regulate private health insurances as well.

The Instituto de Effectividad Clínica y Sanitaria is an International Network of Agencies for Health Technology Assessment–affiliated HTA agency in Argentina with an active role in HTA activities in Argentina and Latin America and the Caribbean region. It has published more than 120 publications in peer-review journals and more than 200 HTAs that are indexed at the Centre for Reviews and Dissemination of the University of York. Forty percent of the HTA documents were on intervention procedures such as implantable cardiodefibrillators, prosthetic intervertebral discs, and deep brain stimulation. Twenty percent of the documents evaluated diagnostic technologies such as positron emission tomography, multislice computed tomography, and hip arthroscopy, and the remaining 40% evaluated drugs such as gefitinib, etanercept, cetuximab, and interferon [20].

Even though Argentina was the first country in the region to require formal health economic evidence for the adoption of technologies into the mandatory benefit package of social security, this is no longer required. Nevertheless, there is an increasing interest and demand for a more explicit and transparent resource-allocation process that includes HTA as a formal tool to inform decision making, in most of Argentine health care stakeholders.

Colombia

In Colombia, health care expenditures represented approximately 6.9%, 7.6%, and 7.6% of its gross domestic product (about $377, $392, and $472 per capita in health care) in 2008, 2009, and 2010, respectively [21,22].

The Colombian health care system, since 1993, is based on compulsory insurance whereby the government mediates and controls the health care system in the country. Law 100 establishes that the Ministry of Health is responsible for the coordination, control, and direction of centers of health. Health insurance in the country can be viewed as part of a contributory system, for people with formal employment, or a subsidized system, for a low-income population. People from both systems can benefit from health providing institutions Empresas Promotoras de Salud [EPS] including hospitals, clinics, laboratories, and pharmaceutical services [23]. This law also requested the creation of the National Institute for Drug and Food Surveillance Colombia, or Instituto Nacional de Vigilancia de Medicamentos y Alimentos, the agency responsible for the regulation and approval of drugs for use in the country [23].

In 2007, the Colombian Congress approved the creation of a Health Regulation Commission La Comisión de Regulación en Salud (CRES) [24]. It was established to define and modify a compulsory basic health care plan (POS); to define the unit of capitation payment (premium that the system pays to the EPS to finance POS) for the contributory and subsidized systems per annum; to define the payment criteria for the payments provided in order to regulate the access to health services; and to establish and update on an annual basis a unified system of fees, including fees for health professionals [24].

The POS covers services, procedures, pharmaceuticals, and others and, since 2008, has to provide the same coverage for both contributory and subsidized systems. All that is not included in the benefit plan (POS) is reimbursed by the Fund for Solidarity and Guarantees. There are two approaches to obtain reimbursement in Colombia: the first is through a scientific panel (comisión técnico científica), and the second is through legal actions for the protection of fundamental rights (tutelas) [25].

In 2010, a bill was passed to Senate to eliminate reimbursement. In 2011, the Ministry of Social Protection passed the resolution 3026/2011 that establishes maximum reimbursement values for pharmaceuticals not included in the benefit plans made by Fund for Solidarity and Guarantees [25,26].

Although there is a growing need to perform HTA to assist in the decision-making process for reimbursement, Colombia has never used pharmacoeconomics to inform reimbursement decisions in the country. Currently, there is a methodological guideline for the development of evidence-based clinical practice guidelines. This methodological guideline includes a chapter on economic evaluation of clinical recommendations (not reimbursement). In 2011, law 1438, which amends the social security system in health, stated that it “Empowers the Ministry of Social Protection, to create an Institute for Health Technology Assessment, which is to be a non-

Table 1 – Characteristics and differences of health care systems and HTA in four Latin American countries.

	Mexico	Brazil	Argentina	Colombia
Health care system	Public and private	Public and private	Public and private	Public and private
Regulatory	COFEPRIS	ANVISA	ANMAT	INVIMA
HTA	Since 2003, pharmacoeconomic studies are required as part of approval decision making. In 2004, CENETEC was established to perform and regulate HTA.	In 2003, CMED was created to evaluate cost of drugs approved in the country. HTA was established in Brazil in 2006, and it is now responsibility of the CONITEC (2011).	There is no centralized/ national HTA system in place.	There is no HTA system in place. HTA decisions in Colombia are based on data from NICE.

ANMAT, Administración Nacional de Medicamentos, Alimentos y Tecnología Médica; ANVISA, Agência Nacional de Vigilância sanitária; CENETEC, Centro Nacional de Excelencia Tecnológica en Salud; CMED, Chamber of Medicine; COFEPRIS, Comisión Federal Para la Protección Contra los Riesgos Sanitarios; CONITEC, Comissão Nacional de Incorporação de Tecnologias; HTA, health technology assessment; INVIMA, Instituto Nacional de Vigilancia de Medicamentos y Alimentos; NICE, National Institute for Health and Clinical Excellence.

profit and private- public institution" [27]. In an attempt to share the risk in Colombia, there are a number of methods for risk adjustment such as co-payment and premium adjustment by age, region, and gender. Similar to Argentina, Colombia has no experience in payment for performance contracts or conditional reimbursement with the device or pharmaceutical industry.

At this point, the impact of economic and humanistic data is currently considered only for clinical practice guidelines; as an example, a budget impact analysis was done to update the POS but was not used by the CRES. There are no centers of excellence in Colombia, but only small groups with minimal experience. At this time, the National Institute for Health and Clinical Excellence has great influence; it is the official consultant for the development of clinical practice guidelines in Colombia.

Comparison of Health Care Systems and HTA in the Four Countries

Table 1 shows a summary of the main characteristics and differences in terms of HTA implementation in the four Latin American countries that are being discussed in this article. Although all countries have similar health care systems, with a mix of public and private sector, only Mexico and Brazil have a national agency responsible for HTA in their respective countries. In Argentina, there are several HTA agencies; however, there is no centralized agency to provide decisions for the entire country. Colombia does make reimbursement decisions; however, this is not dependent on submitted cost and pharmacoeconomic studies but on decisions made by the National Institute for Health and Clinical Excellence—the UK agency—to inform decisions made in its own country.

It is also important to mention that none of the countries listed in this article makes decisions regarding drug approval on the basis of cost but on efficacy and safety. Still, cost discussions by the regulatory agencies are needed to establish the drugs that will be eligible to enter the formulary of each country, and consequently have their cost reimbursed by the public sector of the country.

There is a clear trend reflecting the importance that Latin American health care systems are paying to the concept of incorporating new technologies that are viewed as offering good value proposition.

It is evident that HTA has been formally used to shape benefit packages in a number of Latin American countries. Pharmacoeconomic guidelines are more apparent among some of the four Latin American countries (Brazil and Mexico) for their local needs in terms of regulation along with common country unions.

In the future, the Latin American region needs to increase drug access along with implementing cost-containment measures in their public sector, to improve quality and health outcomes for the population. Moreover, the health care decisions such as approval of drugs and interventions will need to account not only for safety and efficacy but also cost to ensure better economic outcomes in a region with limited resources.

Source of financial support: Bristol-Myers-Squibb, Princeton, NJ, funded this study.

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